DOCUMENT RESUME

ED 315 580 CE 054 051

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TITLE "Certified" Laboratory Practitioners and the Accuracy of Laboratory Test Results.
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PUB DATE Mar 88
NOTE 4p.
PUB TYPE Journal Articles (080) -- Reports - Research/Technical (143)
JOURNAL CIT AMT Events; p35-37 Mar 1988

EDRS PRICE MF01/PC01 Plus Postage.
DESCRIPTORS *Certification; *Competence; *Laboratories; Laboratory Procedures; Medical Services; *Medical Technologists; Professional Services; Research Problems; Test Reliability; *Test Results
IDENTIFIERS *Illinois

ABSTRACT

An attempt to replicate a study of the accuracy of test results of medical laboratories was unsuccessful. Limitations of the obtained data prevented the research from having satisfactory internal validity, so no formal report was published. External validity of the study was also limited because the systematic random sample of 78 licensed laboratories (of 222) in Illinois did not include hospital laboratories, which were not licensed. The independent variable was the proportion of individuals of a given certification affiliation to the total number of personnel employed in a given laboratory. The dependent variable was reported accuracy on the College of American Pathologists proficiency tests. Data were collected from the Illinois Department of Public Health. Proficiency test data, from 1986, were available for only 27 of the laboratories in the original random sample. Personnel data were from September 1987. The time lag between proficiency test and personnel data was of primary concern regarding the internal validity of the study, as it was possible that currently employed laboratory personnel were not responsible for testing performed at a given laboratory 18 months earlier. In addition, certification status on employment records was not required by the State of Illinois. Solid evidence for the accuracy of laboratory results should be derived from comparisons made at the level of the individual, since individuals actually perform tests. (Two references are included in the document.) (CML)

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"Certified" Laboratory Practitioners and the Accuracy of Laboratory Test Results

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ABSTRACT

A salient issue in the medical laboratory profession involves the relationship between practitioners' credentials and the accuracy of laboratory results that they deliver. Several recent articles have been published addressing this topic. One study assessed the relationship between the proportions of "certified" personnel employed at a given laboratory and the accuracy of results that the laboratory produced. In an attempt to elaborate upon the definition of "certified" technologists, a similar study was planned, and the present discussion describes the methodology considered. In the course of collecting data for this study, several procedural anomalies surfaced. These characteristics, inherent in the variable selection and data source, prevented the present authors from having confidence in straightforward conclusions based on the design described. Interpretations of other research based on similar designs should be made with the caveats outlined herein.

The notion that laboratories employing certified personnel produce more accurate results on proficiency tests than those employing non-certified laboratorians has again surfaced in the literature. In one of the most recent studies, Lunz, *et al.* (1987) state that those laboratories employing a greater proportion of certified technologists produce more accurate results than laboratories employing a smaller proportion of certified technologists. The study on which this assertion is based considers only registrants of the American Society of Clinical Pathologists as "certified." In an effort to extend the above authors' definition of "certified technologist" to include laboratory practitioners certified by agencies other than the American Society of Clinical Pathologists, American Medical Technologists planned a similar exploratory study based on the same data source as, and modeled after the Lunz, *et al.* research. However, in the course of conducting the present study, several methodological and procedural anomalies surfaced. Specifically, in the authors' opinion, limitations of the obtained data prevented the present research from having satisfactory internal validity (see Cook and Campbell, 1979). It is for this reason that the authors decided not to publish a formal report of the research.

It has been recognized that conducting criterion-related research in the certification context is necessary yet difficult to execute because of a lack of available valid criterion measures. Although data gained from the present research may represent an independent criterion measure, there are several inherent characteristics of the data which prevented the investigators from having confidence in any conclusions regarding individual laboratorians or distinct credentialing agencies. Below is a brief overview of the data collection plan, followed by concerns regarding the validity of any findings based on the data. Several rival hypotheses compete to explain the obtained results at different stages of the research process, and will be discussed.

A systematic random sample of 78 laboratories was drawn from all licensed laboratories within the State of Illinois (N=222). It should be noted that the use of only licensed laboratories precludes the consideration of a rather large number of facilities and practitioners, because hospital laboratories in Illinois are omitted. This is one generalizability limitation of the present research, which would clearly diminish the external validity of the study.

As with the Lunz, *et al.* study, the present research attempted to relate laboratory personnel composition to accuracy of overall laboratory results. The independent variable was represented by the proportion of individuals of a given certification affiliation, to the total number of personnel employed in a

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given laboratory. The dependent variable was reported accuracy on the College of American Pathologists (CAP) proficiency tests. Specifically, accuracy was represented by the proportion of correct laboratory test results to the total number of tests to which the laboratory subscribed. (Proficiency tests conducted by the American Association of Bioanalysts were also considered. However, this data source reported "exceptions" only, and proportions, therefore, could not be calculated).

All data were collected from the Illinois Department of Public Health. Personnel and proficiency testing data were obtained from the Clinical Laboratory and Blood Bank Section and Laboratory Improvement Section, respectively. It should be noted that records of this type are only collected and maintained by several sources (which include agencies within the states of Illinois and California).

Information on *proficiency test* accuracy was obtained from records on each sampled laboratory for the year of 1986, the most recent year for which complete data were available. However, *personnel* data could only be obtained from current state records (as of September, 1987) for each sampled laboratory. The time-lag between proficiency test and personnel data was of primary concern regarding the internal validity of this study. It is possible that currently employed laboratory personnel were not responsible for proficiency testing performed at a given laboratory 1½ years prior.

Proficiency testing information was gathered for as many of the 78 randomly selected laboratories as possible. It was discovered that only 27 of those laboratories had current CAP reports on file. Several alternate possibilities for the lack of this data are viable: 1) laboratories did not yet return results of their proficiency tests, 2) laboratories did not subscribe to CAP surveys, or 3) laboratories had no exceptions in their tests (only reports for laboratories with exceptions to the CAP surveys are filed). Overall, only one third of the original random sample yielded usable information. Information regarding the remaining two thirds of the sample is vulnerable to a number of alternate interpretations.

In addition to attrition, the investigators encountered several other limitations regarding the use of the above data for this study. For example, designation of certification status on employment records is not required by the State of Illinois. Therefore, some sampled laboratories may contain more certified practitioners than was indicated. Furthermore, dual certifications may or may not be indicated on employment records. Such limitations diminish the confidence that can be placed on interpretations involving particular credentialing agencies. In addition, the sample yielded very low numbers of individuals affiliated with several distinct credentialing agencies, therefore preventing meaningful analysis along this dimension.

Regarding the generalizability of findings, other investigators have shown that "Illinois laboratories represent a reasonable sample of laboratories in terms of size and description of practice when compared with a national sample" (Lunz, *et al.*, 1987, p. 548). However, it may be useful to consider additional variables in assessing the representativeness of the Illinois sample. Furthermore, because the methods of monitoring and reporting laboratory quality are particular to perhaps only Illinois and California, procedural replications confirming the generalizability of findings to other states may not be possible.

It is recognized that a number of methodological differences separate the present review from the study conducted by Lunz, *et al.* However, overall, it may be a moot point to address *proportions* of practitioners employed by laboratories. Solid evidence for the accuracy of laboratory results should be derived from comparisons made at the level of the *individual*, since individuals actually perform tests.

Consider what may be termed a "best technician" theory in terms of the present study. It is reasonable to assume that only one practitioner performs a given laboratory test. It is also conceivable that laboratories employ their "best" technician, regardless of professional affiliation, to respond to proficiency surveys. Therefore, it may be unclear as to who is performing the testing in this study. As a result, any conclusions regarding proportions of employees, or correlations based on such proportions, may not have a straightforward interpretation.

Matters of sampling methodology and statistical treatment of the data may become inconsequential, however, if assumptions underlying the independent and dependent variable selection are tenuous. Overall, if comparisons of individual performance are

to be made, it would be advantageous to restrict analyses to that level of inquiry.

Generally, the information as used in the present study not only prevented the investigators from establishing external validity (generalizability of findings), but more importantly, prevented them from establishing satisfactory internal validity as well. As a result, the present investigators feel that few straightforward conclusions are warranted on the basis of the data that were reviewed. Furthermore, studies utilizing a similar data base should also be interpreted with discretion.

References

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